UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,044	09/17/2003	Katsuya Satoh	1975.1002	2743

21171 7590 02/21/2007

STAAS & HALSEY LLP
SUITE 700
1201 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,044	SATOH ET AL.	
	Examiner	Art Unit	
	David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,10 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,10 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

AMENDMENT ENTRY

Amendment of 11/27/06 has been entered. Claims 1, 5, 10 and 14 are pending. and 14 are under examination. The amendment has entered no new matter.

OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN

The amendment has overcome previously stated issues as follows:

The objection to claims 1 and 5 under 37 CFR 1.75.

The objection to claims 12 and 16 under 37 CFR 1.75, due to their cancellation.

The rejection of claims 1-2 and 5-6- under 35 USC 112, 1st paragraph, with respect to written description.

The prior art rejection under 35 USC 102(a) over Narumi et al (JP 2003052376). The certified translation of the priority document has overcome this basis of rejection. The priority document supports all limits of the instant claims, including the added recitation of "in situ".

The prior art rejection under 35 USC 103(a) over Narumi et al (JP 2003052376) in view of Chaubron et al. The certified translation of the priority document has overcome this basis of rejection under 102 (a). Thus the 103 rejection has been withdrawn.

OBJECTION(S)/REJECTION(S) OF RECORD MAINTAINED

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 10 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. Applicant was not in possession of the genus of proteins "derived from" the Deinococcus radiodurans PrpA protein of SEQ ID NO: 1 that would bind to a DNA strand break.

Claims 1, 5, 10 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the case in which the PrpA protein is one having SEQ ID NO: 1, does not reasonably provide enablement for the case in which the PrpA protein is one "derived from" the Deinococcus radiodurans PrpA protein such that it ends up having an amino acid sequence other than that of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the method or make the kit of the invention commensurate in scope with these claims.

As previously stated, for both the 112 written description and the 112 scope of enablement rejections, no PrpA protein had been described, except that having SEQ ID NO:1, and the use of no PrpA protein had been enabled, except in the case in which the PrpA protein is one having SEQ ID NO:1 (emphasis added). Additionally, it was previously stated (action of 6/27/06 at page 4) that "the examiner considers 'derived from' to broadly encompass any derivatized forms of such isolated proteins; thus any such isolated protein could be modified by chemical derivatizing techniques or by genetic engineering". Instantly, both claims 1 and 5 still recite "derived from Deinococcus radiodurans (SEQ ID NO: 1)". The examiner thus considers the claim scope as encompassing derivatized forms of SEQ ID NO: 1, such as forms that have been modified by chemical derivatizing techniques or by genetic engineering.

It is noted that applicant considers that according to the amendment, "it is clearly described that the PprA protein used in the invention of claims 1 and 5 consists simply of the protein having an amino acid sequence of SEQ ID NO: 1" (see page 5 of amendment filed 11/27/06). It is also noted that applicant has urged that "it is respectfully submitted that the Specification provides enablement under 35 U.S.C. §112, first paragraph, for the case in which the PprA protein is one having SEQ ID NO:

1" (see page 6 of amendment filed 11/27/06). The examiner notes that, despite these urgings, applicant's claims do not recite "consists of" SEQ ID NO: 1, and applicant's claims do not recite "having" SEQ ID NO: 1. Applicant's urgings are not commensurate with the scope of the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Narumi et al (US 2003/0143707), for reasons of record.

The US document is properly cited under 102(e), since the inventive entity is different from that instantly, and since the 102(e) date is before applicant's foreign priority date.

Narumi et al disclose a kit containing the PrpA protein and an antibody thereto; see para. [0055]. The PrpA protein of the reference has the same sequence as that instantly. The antibody may be monoclonal or polyclonal; see para. [0049]. All components of the instant kits are thus shown.

Applicant has urged that the rejection is overcome because the kit of the reference is not for the in situ detection of DNA strand breaks. Irrespective of whether the references teaches the in situ detection of DNA strand breaks, or an equivalent thereof, it is noted that the instant limitation concerning the in situ detection of DNA strand breaks merely pertains to an intended use of the kit components. Since there is nothing different about the physical/chemical characteristics of the PprA protein or of the antibody in a kit intended for the detection of in situ detection of DNA strand breaks,

versus the PprA protein or the antibody in the kit of Narumi et al, the kit remains anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Namuri et al in view of Chaubron et al (US 6,309,838), for reasons of record.

Namuri et al have been noted supra under 102 (e) for teaching the PrpA protein and antibodies of the instant kits. They teach that these reagents may be used to detect strand breaks in DNA; see, for example, para. [0055]. They do not give the details of the steps involved. Chaubron et al show the steps that one can use in the case in which one uses a DNA binding protein (ligand) that recognizes DNA damage, including strand breaks, and also uses an antibody to detect the protein (ligand) bound to damaged DNA. See, for example, col. 2, line 60-col. 3, line 1; col. 9, lines 25-36; col. 10, lines 1-19 and 50-62. Since the PrpA protein of Namuri et al is one that binds to damaged DNA, and is thus a member of the genus of DNA binding proteins (ligands) taught by Chaubron et al, it would have been obvious to use the PrpA protein of Namuri et al in any detection method taught by Chaubron et al.

Applicant has urged that the rejection is overcome because the secondary reference does not teach the in situ detection of DNA strand breaks. This argument is unconvincing because Chaubron et al teach "immunohistological testing" at para. [0055]. It is clear that applicant considers "immunohistological testing" as falling within the scope of in situ detecting, since applicant has taught the examining of "tissue sections" in the context of detecting in situ DNA stand breaks (para. spanning spec. pp 6-7). Even if applicant did not have this specific teaching, anyone of ordinary skill would have considered "immunohistological testing" as inherently involving "in situ detecting",

since histological methods involve the preparation of tissue sections in which the architecture is preserved at both the tissue and the cellular levels by means of fixation; any DNA strand breaks detected would thus be inherently detected within the cell nuclei where the DNA has been fixed (i.e. in situ).

Applicant's arguments filed 11/27/06 have been fully considered but they are not persuasive for the above reasons.

FINALITY

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONTACTS

Any inquiry concerning this communication from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 2/12/07 DAS

David A Saunders

DAVID A. SAUNDERS
PRIMARY EXAMINER